UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,705	03/09/2004	Keun-sik Kim	AM101338	4219

25291 7590 07/15/2005

WYETH
PATENT LAW GROUP
5 GIRALDA FARMS
MADISON, NJ 07940

EXAMINER	
DAVIS, BRIAN J	

ART UNIT	PAPER NUMBER
1621	

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/797,705	KIM ET AL.	
	Examiner	Art Unit	
	Brian J. Davis	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-19 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/22/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 12, 15 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regard to substituents R_1 and R_2, their exact orientation as "ortho or para substituents" is unclear. That is, are they ortho or para to each other or to the remainder of the molecule?

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how R_1 and R_2 can both be substituents on the same carbon of the benzene, vide supra.

The remaining claims are also rejected under 35 USC 112, second paragraph, as claims which depend from indefinite claims are also indefinite. *Ex parte Cordova*, 10 USPQ 2d 1949, 1952 (PTO Bd. App. 1989).

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 02/50017 A1, cited by applicant in the IDS. The reference teaches the instant hydrogenation reaction of a set of applicant's starting nitrile compounds (page 1, last full paragraph) preferably over Raney nickel or Raney cobalt catalysts (page 3, third full paragraph) and preferably at a temperature of 20-80°C (page 5, sixth full paragraph) and preferably in the presence of methanol or ethanol (page 5, third full paragraph). The catalysts may be present in about 0.1-500% by weight of the starting material (page 5, fourth full paragraph). The amine products of the above reaction may be alkylated and isolated as the hydrochloride salt (page 7, last full paragraph).

Claims 15 and 16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by *J. of Medicinal Chemistry* (1990), 33(10), p. 2899-2905. The reference teaches applicant's compound (1-[2-amino-1-(4-methoxyphenyl)ethyl]cyclohexanol) as one of a series of compounds evaluated for antidepressant activity (page 2899 last full sentence). Such an evaluation necessitates their use in a composition, for instance, as their water-soluble salts (page 2900 first sentence under the "Chemistry" heading).

With regard to the limitation of the instant composition being "substantially free of phenylalkylamine impurities," this limitation is intrinsic to the prior art

composition because the compound is first isolated as a (pure) crystalline solid (page 2902 compound (5) under the "Experimental" heading).

With regard to the limitation of the instant composition being prepared from a compound prepared by the method of instant claim 1, this limitation is not relevant to patentability. This is so because the instant claims are product-by-process claims. And even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) MPEP 2112.02.

Claims 17-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 00/59851. The reference teaches "derivatives of venlafaxine such as, but not limited to, (±)-O-desmethylvenlafaxine, (±)-N-desmethylvenlafaxine..." in pharmaceutical compositions (page 5 line 34).

With regard to the limitation of the instant composition being "substantially free of phenylalkylamine impurities" and specifically "4-methoxyphenethylamine impurities," this limitation is intrinsic to the prior art composition because the composition is made from compounds synthesized without recourse to hydrogenation (Examples 2 and 3).

With regard to the limitation of the instant composition being prepared from a compound prepared by the method of (ultimately) instant claim 1, this limitation is not relevant to patentability. This is so because the instant claims are product-by-process claims. And even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) MPEP 2112.02.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BRIAN DAVIS
PRIMARY EXAMINER

Brian J. Davis
July 11, 2005